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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,967	04/24/2000	MATTI KORPELA	2328-117	8859

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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 01/07/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,967

Applicant(s)

KORPELA ET AL.

Examiner

Bradley L. Sisson

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-10 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As presently worded, the observation of any increase in signal, even if it is not statistically significant, is to be interpreted as being indicative of Tetracycline being present when in fact no Tetracycline would be present. In short, changes in background signal would be interpreted as being a positive signal for the presence of Tetracycline. The specification has not been found to set forth a repeatable procedure whereby one would be able to determine the presence of Tetracycline when the change signal is not statistically significant.

3. The specification has been found to set forth examples whereby *E. coli* strain K12 was transfected with either pTetLux1 or pTetLuc1. No other construct and no other strain were used. At page 18 of the specification applicant cautions that the presence of calcium and Magnesium ions will chelate with Tetracycline "and loose their antimicrobial and induction activity in our assay." The claimed method, however, does not recite such basic and critical limitations. Accordingly, the claimed method has been interpreted as encompassing the use of strains of any prokaryote, including other strains of *E. coli*, that are not sensitive to Tetracycline. The claimed

method is also considered to encompass the performance of the claimed method steps wherein calcium and magnesium ions are present. The presence of either ion, whether or not a Tetracycline-sensitive strain of *E. coli* is used, will cause the method to generate false results.

4. In view of the explicit and narrow teachings provided by the disclosure, the specification has not been found to enable the full scope of the claimed invention. In order for one of skill in the art to practice the full scope of the claimed invention, wherein the guidance is lacking, would require the public to engage in trial-and-error evaluation of alternative embodiments. Such efforts are not considered to constitute routine experimentation but rather, are considered to constitute undue experimentation. Accordingly, and in the absence of convincing evidence to the contrary, the claims are not enabled by the disclosure.

Response to argument

5. At page 6 of the response filed 19 September 2002, Paper No. 20, agreement is reached in that the specification contemplates the use of the tet system with numerous bacterial strains and with numerous samples. Such contemplation, however, does not rise to the level of full enablement but rather, only constitutes an invitation for others to experiment in certain areas.

6. At page 9, applicant asserts that any strain of bacteria can be used so long as the proper regulatory elements are incorporated. Argument is also advanced that "[a]ny sample can be utilized, so long as it is eventually mixed with the cells in liquid form."

7. The above arguments have been fully considered and have not been found persuasive. The specification, as noted above, disclosed the use of a Tetracycline-sensitive strain of *E. coli* and then uses but two constructs. No other strain of microbe, Tet-sensitive or not, is disclosed, and no other suitable construct is disclosed. Furthermore, the specification states explicitly at

page 18 that their assay is ineffective when Ca^{2+} and Mg^{2+} ions are present. Clearly, the method cannot be practiced with any sample.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-10 and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
10. Claim 1 is indefinite with respect to how a "liquid [sample is] from a . . . solid sample." Claims 2-10 and 16-19, which depend from said claim 1, fail to overcome this issue and are similarly rejected.
11. The term "higher" in claim 1 is a relative term which renders the claim indefinite. The term "higher" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Claims 2-10 and 16-19, which depend therefrom, fail to overcome this issue and are similarly rejected.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. US 2002/0172974 A1 Coleman et al.
- b. 6,277,632 B1 Harney.

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c. US 6,329,160 B1 Schneider et al.

d. US 4,861,709 Ulitzur et al.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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17. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
December 15, 2002